PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 257-Q-01-PCT	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/IL2007/001399	International filing date *(day/month/year)* 13 November 2007 (13.11.2007)	Priority date *(day/month/year)* 13 November 2006 (13.11.2006)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant Q-CORE LTD.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 19 May 2009 (19.05.2009)
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Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*)	04 JUN 2008
Applicant's or agent's file reference 257-Q-01-PCT	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/IL07/01399	13 November 2007 (13.11.2007)	13 November 2006 (13.11.2006)

International Patent Classification (IPC) or both national classification and IPC

IPC: **F04B 43/08**(2006.01),**43/12**(2006.01),**45/06**(2006.01)
USPC: 417/474,475,476,477.1-477.14

Applicant

Q-CORE LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☒ Box No. VII — Certain defects in the international application
- ☒ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis(b)* that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	07 May 2008 (07.05.2008)	Devon Kramer Telephone No. 571-272-3700

5/21/08

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

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PCT/IL07/01399

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
   - ☒ the international application in the language in which it was filed
   - ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material
      - ☐ a sequence listing
      - ☐ table(s) related to the sequence listing

   b. format of material
      - ☐ on paper
      - ☐ in electronic form

   c. time of filing/furnishing
      - ☐ contained in the international application as filed.
      - ☐ filed together with the international application in electronic form.
      - ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	NONE	YES
	Claims	1, 3, 4, 5, 7	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	2, 6	NO
Industrial applicability (IA)	Claims	1-7	YES
	Claims	NONE	NO

2. Citations and explanations:

Please See Continuation Sheet

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 1 is objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: Line 10 of claim 1 reads "e.g., one potion of the pump," but should read "e.g. one portion of the pump".

Claim 5 is objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: Line 14 of claim 5 reads "e.g., one potion of the pump," but should read "e.g. one portion of the pump".

Claim 5 is also objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: Part iii of claim 5 (lines 32-34) recites the same method step as part i (lines 25-27). It is unclear whether this is an unintentional mistake.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 1 and 5 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 1 and 5 were found indefinite for the following reason(s): Claims 1 and 5 both make use of the term 'preferably', in lines 7, 10, and 16 of claim 1, and in lines 11, 14, and 20 of claim 5. It is unclear whether the term 'preferably' refers to structure that must be part of the invention, or whether it refers to a preferred, but not required, structure.

Claim 1 and 5 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 1 and 5 were found indefinite for the following reason(s): Claim 1 refers to "said portion of said pump" in line 16, and claim 5 refers to "said portion of said pump" in line 20. It is unclear which portion of the pump "said portion" refers to.

Claim 3 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim 3 was found indefinite for the following reason(s): Claim 3 states that the barrel-saddle hinged mechanism "provides for" a single handed integration. It is unclear whether the barrel hinge must be operated by a single hand, or must merely provide for single hand operation.

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Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:
Claims 1, 3, 4, 5, and 7 lack novelty under PCT Article 33(2) as being anticipated by Goldor et al.

In Reference to Claim 1

Goldor et al. teach an OPEN/CLOSE mechanism comprising a passive mechanical interface (MS) (housing (6)) and a finger-type peristaltic infusion pump (DDS) (pump (2)); said MS is an elongated member characterized by upstream and downstream opposite ends (fluid would be pumped from one end to the other via conduit (18)), integrally accommodating a portion of a flexible infusion-tube (see paragraph [0020]), the main longitudinal axis of said tube is parallel to the main longitudinal axis of said MS (see figure 1); said MS comprises (i) a saddle-like catch (saddle), located at one end of the MS, preferably the downstream end (the annular part of hinge (8) is partially shaped like a saddle); and (ii) a toothed interface located at the opposite end of the MS (projections (10)), preferably the upstream end, said interface is adapted to accommodate at least one catch securely and reversibly fastening said MS in an OPEN configuration (see paragraph [0019]); said finger-type peristaltic infusion pump comprises (i) a barrel-like axle (barrel) (the cylindrical inner portion of the hinge that is part of the pump body (4) forms a barrel surrounded by the annular portion of the hinge), located e.g., one potion of the pump, preferably the downstream portion; said barrel is adapted to fit said saddle by means of shape and size such that a two-parts hinge is when said saddle and barrel are integrated (see hinge (8) in figure 2b); said hinge reversibly facilitates said MS in either OPEN (MS is away from the finger-type peristaltic infusion pump) configuration or CLOSE (MS incorporates with the finger-type peristaltic infusion pump) configuration (see paragraph [0019]); and, (ii) at least one spring catch (projections (10) along with spring loaded tab (34) form the catch), located at said portion of said pump, preferably upstream portion, said catch is adapted to lock- on said toothed interface and reversibly yet effectively lock said MS at said CLOSE configuration; wherein by stepwise incorporation of said MS with said finger-type peristaltic infusion pump provides an easy and mistake-proof OPEN/CLOSE three steps mechanism (see paragraph [0019]): first step comprises incorporating said saddle with said barrel in said OPEN configuration (the saddle is always incorporated with the barrel to form hinge (8)), such that one, i.e., Roll, degree of freedom in said three dimensional mutual orientation is eliminated; second step rotatably closes said MS in a lever-like manner, and the third step comprises incorporation of said spring catch within said toothed interface, so that other five DOFs are eliminated and a secure CLOSE configuration is obtained (see paragraph [0019]).

In Reference to Claim 3

Goldor et al. teach the OPEN/CLOSE mechanism of claim 1, wherein said barrel-saddle hinged mechanism provides for a single-handed MS-DDS integration ability (The hinge/lever apparatus of Goldor et al. is capable of being operated with one hand, since one hand would be used to steady the pump body (4) while the other hand would actuate the lever housing (6) to place it in the closed position).

In Reference to Claim 4

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Supplemental Box
In case **the space in any of the preceding boxes is not sufficient.**

Goldor et al. teach the OPEN/CLOSE mechanism of claim 1 (see the rejection of claim 1 above), wherein said flexible infusion tube is accommodated within said MS by means of two connectors (the holes in each side of the housing (6) serve to stabilize the tube contained in passage (18)); said connectors immobilize said tube and stabilizing it towards forces applied in parallel to said tube's main longitudinal axis, i.e., from the patent and/or supply lines.

In Reference to Claim 5

Goldor et al. teach A method for providing an OPEN/CLOSE mechanism by both an elongated passive mechanical interface (MS) and a finger-type peristaltic infusion pump (see paragraph [0019]); said method comprising: a. obtaining (in order to perform the method specified in paragraph [0019], the apparatus described must be obtained) an OPEN/CLOSE mechanism comprising a passive mechanical interface (MS) (housing (6)) and a finger-type peristaltic infusion pump (DDS) (pump (2)); said MS is an elongated member characterized by upstream and downstream opposite ends (fluid would be pumped from one end to the other via conduit (18)), integrally accommodating a portion of a flexible infusion-tube (see paragraph [0020]), the main longitudinal axis of said tube is parallel to the main longitudinal axis of said MS (see figure 1); said MS comprises (i) a saddle-like catch (saddle), located at one end of the MS, preferably the downstream end (the annular part of hinge (8) is partially shaped like a saddle); and (ii) a toothed interface located at the opposite end of the MS (projections (10)), preferably the upstream end, said interface is adapted to accommodate at least one catch securely and reversibly fastening said MS in an OPEN configuration (see paragraph [0019]); said finger-type peristaltic infusion pump comprises (i) a barrel-like axle (barrel) (the cylindrical inner portion of the hinge that is part of the pump body (4) forms a barrel surrounded by the annular portion of the hinge), located e.g., one potion of the pump, preferably the downstream portion; said barrel is adapted to fit said saddle by means of shape and size such that a two-parts hinge is when said saddle and barrel are integrated (see hinge (8) in figure 2b); said hinge reversibly facilitates said MS in either OPEN (MS is away from the finger-type peristaltic infusion pump) configuration or CLOSE (MS incorporates with the finger- type peristaltic infusion pump) configuration (see paragraph [0019]); and, (ii) at least one spring catch (projections (10) along with spring loaded tab (34) form the catch), located at said portion of said pump, preferably upstream portion, said catch is adapted to lock- on said toothed interface and reversibly yet effectively lock said MS at said CLOSE configuration; and, b. stepwise incorporating said MS with said finger-type peristaltic infusion pump provides an easy and mistake-proof OPEN/CLOSE three steps mechanism (see paragraph [0019]): i. incorporating said saddle with said barrel (the saddle is always incorporated with the barrel to form hinge (8)) in said OPEN configuration, such that one, i.e., Roll, degree of freedom in said three dimensional mutual orientation is eliminated; ii. rotatably closing said MS in a lever-like manner (the body (6) acts as a lever about hinge (8)), and the third step comprises incorporation of said spring catch within said toothed interface, such that other five DOFs are eliminated and a secure CLOSE configuration is obtained (see paragraph [0019] where the projection (10) snaps into place).

In Reference to Claim 7

Goldor et al. teach the method according to claim 5, wherein said stepwise method of incorporating said MS with said finger-type peristaltic infusion pump comprising utilizing a single hand (The hinge/lever apparatus of Goldor et al. is capable of being operated with one hand, since one hand would be used to steady the pump body (4) while the other hand would actuate the lever housing (6) to place it in the closed position).

Claims 2 and 6 lack an inventive step under PCT Article 33(3) as being obvious over Goldor et al. in view of Moubayed et al.

In Reference to Claim 2

Goldor et al. teach the OPEN/CLOSE mechanism of claim 1, but give no guidance as to the amount of force needed to close the device.

Moubayed et al. teach a similar pivoting pump attachment where the forced used to close the pivoting member is enough to apply a slight amount of compressive pressure to the tubing, but not enough to crush the tubing (see column 14 lines 11-29). Thus Moubayed et al. suggest that the amount of force applied to the lever to close the device is a range that varies from too little force, where the device would not close, to too much force, where the tube would be crushed or the apparatus would break. It would have been obvious to one having ordinary skill in the art at the time the invention was made that the optimum amount of force, in this case 1.2 Kg, would fall somewhere in this range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

In Reference to Claim 6

Goldor et al. teach the method according to claim 5, comprising step of applying force to rotate said MS to its CLOSE configuration, but give no guidance as to the amount of force needed to close the device.

Moubayed et al. teach a similar pivoting pump attachment where the forced used to close the pivoting member is enough to apply a slight amount of compressive pressure to the tubing, but not enough to crush the tubing (see column 14 lines 11-29). Thus Moubayed et al. suggest that the amount of force applied to the lever to close the device is a range that varies from too little force, where the device would not close, to too much force, where the tube would be crushed or the apparatus would break. It would have been obvious to one having ordinary skill in the art at the time the invention was made that the optimum amount of force, in this case 1.2 Kg, would fall somewhere in this range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Claims 1-7 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL07/01399

Supplemental Box
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